K091794

510(k) Summary
(As required by 21 CFR 807.92(a))

JAN 28 2010

A. Submitter Information

Care2 Medical Products, Inc.
1599 Superior Ave, Ste B5
Costa Mesa, CA 92627

Phone Number: 949-481-5713
Fax Number: 949-481-5745
Contact: Jim Barley
Director RA/QA

Trade Name: Care2 Medical Nebulizer

B. Device Information

Trade/Proprietary Name: Care2 Medical Nebulizer

Common name of device: Nebulizer

Classification Name: Nebulizer

Product Code: CAF

Regulatory Class: II

Classification Number: 868.5630

Reason for 510(k): New Device

C. Predicate Device: Hudson Hand Held (T "Up-Draft) Nebulizer

Predicate 510(k) #: K760489

Predicate product code: CCQ

Predicate Device: Circulaire Nebulizer

Predicate 510(k) #: K926055

Predicate product code: CAF

Predicate Device: Airlife Misty Max 10 Nebulizer

Predicate 510(k) #: K023602

Predicate product code: CAF

D. Device Description

The Care2 Medical Small Volume Nebulizer is a single patient use device. The device is filled with a liquid medication and connected to an air source via flexible tubing. Once the gas comes in contact with the liquid medication, the gas shatters the liquid into small particles. These particles then hit a baffle which further reduces the size of the particles. The smaller particles are administrated to the patient as the patient breathes. The larger particles settle inside the device returning the mist to a liquid to repeat the process until a majority of the medication is nebulized.

The Care2 Medical Nebulizer is unique in that it has a side port which allows the user to add medication to the nebulizer without removing the top.

The Small Volume Nebulizer is packaged non-sterile in a polyethylene bag.

E. Statement of Indications for Use

The Care2 Medical Nebulizer is a pneumatic nebulizer intended to aerosolize physician prescribed inhalation solutions for inhalation by infant, pediatric and adult patients. It's use is indicated whenever a physician or healthcare professional administers or prescribes inhalation solutions to a patient using a small volume nebulizer. The device is single patient use.

F. Comparison of Required Technological Characteristics:

The Care2 Medical Nebulizer has the same design, function and intended use as the Hudson Hand Held (T "Up-Daft") Nebulizer, Airlife Misty Max 10 Nebulizer and the Circulaire Nebulizer.

The Care2 Medical Nebulizer Bottle is approximately the same size and shape as the Hudson Hand Held (T "Up-Daft") Nebulizer, Airlife Misty Max 10 Nebulizer and the Circulaire Nebulizer. Each nebulizer consists of a Nebulizer Bottle, Supply Tubing, Tee Connector and Mouthpiece. The Nebulizer Bottle has a top, bottom and funnel. The top of each Nebulizer can be removed to add medication.

The Care2 Medical Nebulizer, Hudson Hand Held (T "Up-Daft") Nebulizer, Airlife Misty Max 10 Nebulizer and Circulaire Nebulizer tubing assemblies are almost identical. In addition, the TEE Connector, Mouthpiece and Corrugated Tubing are almost identical. Each component is the same size, shape and color.

The Care2 Medical Nebulizer, Hudson Hand Held (T "Up-Daft") Nebulizer, Airlife Misty Max 10 Nebulizer and Circulaire Nebulizer are packaged in a polyethylene bag and are sold as Non-Sterile devices.

The only significant difference between the Care2 Medical Nebulizer, Hudson Hand Held (T "Up-Daft") Nebulizer, Airlife Misty Max 10 Nebulizer and the Circulaire Nebulizer is the side port on the Care2 Medical Nebulizer. The side port on the Care2 Medical Nebulizer allows the health care professional to add medication to the Nebulizer Bottle by inserting the medication pillow through the side port and squeezing the medication into the Nebulizer Bottle.

The Circulaire Nebulizer has a 750 mL bag to store aerosol during exhalation, a one-way valve to prevent exhaled gas from entering the reservoir bag and a variable inspiratory/expiratory resister.

All other differences between the the Care2 Medical Nebulizer, Hudson Hand Held (T "Up-Daft") Nebulizer, Airlife Misty Max 10 Nebulizer and the Circulaire Nebulizer are cosmetic.

G. Summary and Conclusion of Nonclinical and Clinical Tests:

The product/performance requirements for the Care2 Medical Nebulizer were as follows:

All components of the Care2 Medical Nebulizer met the dimensional, visual and functional requirements listed on the part/assembly drawing.

All materials used in the fabrication of the Care2 Medical Nebulizer met the requirements of ISO 10993 Part-1, "Biological Evaluation of Medical Devices".

Particle size distribution testing showed that the performance of the Care2 Medical Nebulizer was substantially equivalent to that of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 28 2010

Steve Islava
C/O Mr. Jim Barley
President
DBA Care2 Medical Nebulizer
1599 Superior Avenue #B5
Costa Mesa, California 92627

Re: K091794
Trade/Device Name: Care2 Medical Nebulizer Model 101/ 202
Regulation Number: 21CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: January 20, 2010
Received: January 25, 2010

Dear Mr. Barley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K091794

Device Name:

Indications For Use:

The Care2 Medical Nebulizer is a pneumatic nebulizer intended to aerosolize physician prescribed inhalation solutions for inhalation by infant, pediatric and adult patients. It's use is indicated whenever a physician or healthcare professional administers or prescribes inhalation solutions to a patient using a small volume nebulizer. The device is single patient use.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

For Tony Watson

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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